

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION) MDL 2804
OPIATE LITIGATION)
THIS DOCUMENT RELATES TO:) Case No. 1:17-MD-2804
Track Three Cases) Judge Dan Aaron Polster
) OPINION AND ORDER REGARDING
) THE EXPERT OPINIONS OF
) PROF. DANIEL C. MALONE

The Pharmacy Defendants move to exclude the opinions and testimony of Prof. Daniel C. Malone. Doc. 3857. Plaintiffs filed a response in opposition and Defendants filed a reply in support. Upon careful review of the parties' briefs and supporting documents, including the expert report of Prof. Malone, for the reasons stated below, Defendants' Motion is **DENIED**, with a minor exception noted below.

Legal Standard

The Court hereby incorporates the legal standard set forth in the Court's Opinion and Order regarding *Track One-A* Defendants' motion to exclude the opinion and testimony of Prof. Meredith Rosenthal. *In re Nat'l Prescription Opiate Litig.*, No. 1:17-MD-2804, 2019 WL 3934597, at *1–*5 (N.D. Ohio Aug. 20, 2019) (Doc. 2495 at 1–10).

Analysis

Daniel C. Malone, M.S., Ph.D., FACMP is a professor of pharmacotherapy at the University of Utah. He practiced pharmacy for the first several years of his career, and has spent the last nearly three decades researching ways to use data available to pharmacies to “improve patient safety.” Malone Rpt. at 1. Until recently, Prof. Malone kept his pharmacist licenses active.

For the past twenty years, Prof. Malone has designed algorithms and written code, using data available to pharmacies, to “identify medication-related safety issues.” *Id.* at 2. Prof. Malone is the recipient of numerous grants and other funding for his research and has published over 195 peer-reviewed papers. Altogether, Prof. Malone has nearly four decades of experience using, analyzing, researching, or otherwise working with various types of data available to pharmacies.¹

Prof. Malone’s opinions are not highly technical or scientific. He draws upon his substantial experience to offer straightforward opinions simply about whether it was technologically feasible for pharmacies to utilize the data they routinely collect, in the usual course of business, to create warnings or alerts that could assist pharmacists to identify potentially inappropriate prescriptions. Prof. Malone concludes, based on his experience in the industry, that it was technologically possible for each of the Pharmacy Defendants to do this. He does not, as Defendants contend, conclude their specific systems were inadequate or they should have used one type of system over any other.

The Defendants assert Prof. Malone’s opinions are inadmissible because he does not use reliable (or a sufficient number of)² sources, nor a reliable methodology. Defendants also assert Prof. Malone’s opinions will not be helpful to the factfinder.³ Plaintiffs respond that, “[f]or this

¹ In Prof. Malone’s words, that data includes, “data from pharmacies, pharmacy administrative claims data, prescriber DEA registration files, electronic health record data, and various healthcare databases including data from insurance companies and various payers such as Medicare, Department of Veterans Affairs, and Medicaid.” Malone Rpt. at 1–2.

² Defendants also assert Prof. Malone did not review any data specific to the individual Pharmacy Defendants, and the information he did review was outdated. However, Prof. Malone explains: “The great thing about pharmacy and pharmaceuticals is that the data fields have largely been standardized across the entire industry for many, many years. As I indicated in my report, the National Council for Prescription Drug Programs has standardized the submission of claims data.” Malone Dep. Tr. at 171:6-14. If the Pharmacy Defendants do not use this standardized data, they are welcome to make that argument at trial; but as it pertains to their *Daubert* motion, evidence regarding what data the Defendants actually used or had access to goes to the weight of Prof. Malone’s testimony, not its admissibility.

³ The Court does not directly address Defendants’ argument that Prof. Malone’s opinions will not be helpful to a jury, because those arguments are explicitly premised on his opinion’s purported lack of reliability, which the Court rejects. See Mot. at 11 (Doc. 3857) (“The lack of reliable methodology underlying Malone’s opinion means that it cannot

kind of testimony, application of the expert's knowledge and experience is, itself, a reliable methodology for which the expert's background and experience provide sufficient indicia of reliability." Response at 7 (citing *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999)).

The Court agrees with Plaintiffs. Where non-scientific expert testimony is involved, "the relevant reliability concerns may focus upon personal knowledge or experience." *First Tennessee Bank Nat. Ass'n v. Barreto*, 268 F.3d 319, 335 (6th Cir. 2001) (citing *Kumho*, 526 U.S. at 150). Prof. Malone inarguably has the requisite personal knowledge and experience to offer his opinions.⁴

The Pharmacy Defendants' concerns might be more persuasive if Prof. Malone had purported to evaluate each of their systems for legal adequacy or some system-specific capability. However, Prof. Malone's expert report does not draw such specific conclusions.⁵ Moreover, Plaintiffs expressly state in their response that "Prof. Malone is not providing any opinions on the exact specifications for what would constitute inappropriate opioid use." Opp. at 14. Accordingly, "Prof. Malone can reliably testify about the **feasibility** of Defendants using this data to alert their pharmacists about potentially inappropriate opioid prescriptions." *Id.* at 13 (emphasis added).

possibly be helpful to the jury in resolving this matter."). As outlined briefly below, however, the Court believes Prof. Malone's opinions and testimony will benefit the jury.

⁴ Defendants do not argue Prof. Malone is not qualified.

⁵ For example, Prof. Malone does not opine on whether any Defendant's system was legally sufficient. Nor does he test any Defendant's systems against a standard. Nor does he define a standard against which to test them. Prof. Malone simply opines, based on his considerable experience and knowledge of the data available to the Defendants, that it would be **possible** to have a system that could alert a pharmacist of potentially suspicious or inappropriate prescriptions. See Malone Rpt. at 2–3. He further, and expressly, does not opine on what constitutes a suspicious prescription or an excessive use of opioids. See Malone Dep. Tr. at 171:6-14 ("Determining, you know, the decision point what is an excessive use of opioids, that is correct, that is not my area of expertise. My area of expertise is creating algorithms that can identify potential problems and assessing those algorithms and using the data that is available to me to help contextualize or make that information useful to the person having to make a decision based on that information.").

As summarized above, Prof. Malone's opinions are relatively benign. Plaintiffs, in their response, and Prof. Malone, at his deposition, draw the Court's attention to a 2013 article by CVS employees describing a system similar to what Prof. Malone describes as possible.⁶ Admittedly, testimony on the feasibility of creating a system that demonstrably already exists might be, by itself, of limited value to the fact finder. However, the Court concludes Prof. Malone's ability to explain the technology behind such a system will nevertheless be helpful to the fact finder, and on that point, Prof. Malone is eminently qualified. *See Fed. R. Evid. 702, 2000 advisory committee notes* ("[I]t might also be important in some cases for an expert to educate the factfinder about general principles, without ever attempting to apply these principles to the specific facts of the case."). Thus, the Court determines that Prof. Malone's opinions are reliable and will be helpful to the jury.

There is one caveat to the Court's opinion. Defendants draw the Court's attention to Prof. Malone's conclusion that "pharmacy chain organizations created, purchased, or aggregated data that could have been used *to reduce the inappropriate use* of opiates and other medications." Malone Rpt. at 7 (emphasis added). This conclusion goes a step beyond Prof. Malone's admitted area of expertise. *See Malone Dep. Tr. at 171:6-8* ("Determining . . . the decision point what is *an excessive use* of opioids . . . is not my area of expertise.") (emphasis added). The identified conclusion assumes that the warnings or alerts Prof. Malone believes are feasible would have reduced opioid ***use*** in Plaintiffs' populations. Such a conclusion is beyond the scope of Prof. Malone's expertise. To the extent Plaintiffs attempt to elicit testimony from Prof. Malone regarding the ***effectiveness*** of the warnings he concludes are feasible, the Court will sustain an

⁶ *See Opp. Ex. 4 at 3, Betses M., Brennan T., "Abusive Prescribing of Controlled Substances—A Pharmacy View."* *N Engl J Med.* 2013; 369: 989-991 ("At CVS, we recently instituted a program of analysis and actions to limit inappropriate prescribing. Our program was intended to identify and take action against physicians and other prescribers who exhibited extreme patterns of use of "high-risk drugs" relative to other prescribers.").

objection to such testimony as outside Prof. Malone's expertise. In other words, Prof. Malone can opine that the Pharmacy Defendants' could have created systems to mine data and alert their pharmacists about potentially inappropriate opioid prescriptions; but he cannot opine these alerts would have led to a reduction of inappropriate use of opioids.

Accordingly, the Pharmacy Defendants' motion to exclude the opinions and testimony of Prof. Daniel C. Malone. (Doc. 3857) is **DENIED**.

IT IS SO ORDERED.

/s/ Dan Aaron Polster August 31, 2001
DAN AARON POLSTER
UNITED STATES DISTRICT JUDGE